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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,597	04/11/2006	Jonathan S. H. Denyer	02-91	7255

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P.O. BOX 3001
BRIARCLIFF MANOR, NY 10510

EXAMINER	
STUART, COLIN W	

ART UNIT	PAPER NUMBER
3771	

MAIL DATE	DELIVERY MODE
05/27/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/535,597	DENYER ET AL.	
	Examiner	Art Unit	
	COLIN STUART	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 May 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/13/06 & 8/22/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 8/22/05 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Note: documents not considered have been crossed through.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The method steps recited in claim 1 are rejected because they are an abstract idea which can be performed by mental processing. Lacking structure the claim is directed to non-statutory subject matter.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the time the person takes to stop..."" in line 6-7. There is insufficient antecedent basis for this limitation in the claim. In addition, it is not clear which disclosed structure is being used to perform the claimed steps such as the controller/microprocessor.

Claim 3 recites the limitation "the first pre-set period of time" in line 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim 14 recites the limitation "the I:E ratio" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claims 2, 4-13, 15-20 and 27 are rejected based on dependency on a rejected claim.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 21 is rejected under 35 U.S.C. 102(b) as being anticipated by Edgar et al. (4,677,975).

In regards to claim 21, Edgar shows a drug delivery apparatus for an aerosolized drug which includes an airflow sensor (14 & 15) for detecting the inhaled airstream, a signaling device 24 arranged to give signals to the person, and a controller 21 which is arranged to control the operation of the signaling device to the patient depending on the input from flow sensor and capable of adjusting a pre-set inhalation time depending on the duration of the patients inhalation measured by the airflow sensors (14 & 15).

In regards to claim 23, Edgar shows a drug delivery apparatus which also includes an aerosol generator 1.

In regards to claim 24, Edgar shows a drug delivery apparatus in which the signaling device is any one or more of: an audio device, a visual device and a vibrator device (see col. 2 ln. 68 - col. 3 ln. 1-2).

In regards to claim 25, Edgar shows a drug delivery apparatus which includes a time 27 which calculates a pre-set period of time for inhalation.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-12, 18-20, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schuster et al. (5,906,202) in view of Mishelevich et al. (5,363,842) and Crockford et al. (2003/0205229).

In regards to claim 1, Schuster discloses a method of aerosolized medication delivery which includes the steps of detecting the commencement of inhalation (col. 13 ln. 19-23), signaling the person to cease inhalation (col. 2 ln. 62-66) after pre-set volume of medicine has been delivered. It does this through a time period for aerosol delivery but does not rely on a specific pre-set time period. However, Mishelevich teaches an inhaler feedback method which detects a time course in which the patient is inhaling (Mishelevich col. 4 ln. 35-39) and compares this to target envelopes (Mishelevich col. 4 ln. 40-44) but directs the patient to change breathing pattern to match pre-set time period instead of changing the pre-set time period to match patient's breathing pattern. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Schuster to include the steps of detecting a pre-set time duration of inhalation and comparison to target envelope as taught by Mishelevich in order to ascertain a more accurate description of the patient's

breathing pattern. However, Crockford also teaches a device which employs a method of gathering data about a patient's previous breathing patterns, such as time duration, and adjusts subsequent breathing patterns to match patient's needs (Crockford para. 0056 ln. 9-15). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Schuster's method to include the steps of adjusting the pre-set time duration as taught by Crockford in order to accommodate to a patient's breathing pattern who may have respiratory problems and cannot change their breathing patterns. Adjustment using the modified Schuster's method would depend on the time the person takes to stop inhaling after signaled to stop as comparison to target envelopes would allow a processing unit to determine the difference between the target envelop and the actual inhalation duration.

In regards to claims 2-4, the modified Schuster's reference adjusts the pre-set time period, or duration, by either increasing or decreasing the period depending on comparison to target envelope for patient (see Crockford para. 0056 and para 0065 ln17-21). The modified Schuster's reference does not explicitly mention threshold times for comparison but such a comparison using two (first and second) threshold values, upper and lower bounds, is well-known in the art and would have been obvious to one of ordinary skill in the art at the time the invention was made. In using these upper and lower threshold values one will be greater than or equal to the second value.

In regards to claims 5-12, the modified Schuster's reference does not explicitly mention the values of the first and second threshold values. However, the values and ranges of values claimed are considered to be a matter of obvious design choice to one

of ordinary skill in the art at the time the invention was made as the modified Schuster's reference method would perform equally well with the claimed values.

In regards to claim 18 and 27, the modified Schuster's reference teaches the step of delivering an aerosolized substance to into at least part of the inhaled airstream (Schuster Abs. ln. 1-3).

In regards to claims 19-20, the modified Schuster's reference teaches the step of ceasing the aerosolized delivery of medication before the end of the inhalation period (see Crockford para 0060 ln. 5-10) but is silent as to a specific time period before the end of inhalation period. However, one of ordinary skill in the art at the time of the invention would have found this to be a matter of obvious design choice as the modified Schuster's method would perform equally as well with the claimed time periods.

8. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schuster et al. (5,906,202), Mishelevich et al. (5,363,842), and Crockford et al. (2003/0205229) as applied to claim 1 above, and further in view of Krumbiegel et al. (5,928,156).

In regards to claim 13, the modified Schuster's reference teaches all the limitations as discussed above including detecting the end of inhalation and calculating the period of inhalation (see Mishelevich col. 4 ln. 35-55) but is silent as to calculating the period between inhalations. However, Krumbiegel teaches a process of respiratory detection which discloses calculating the period between inhalations (see claim 6 of Krumbiegel). It would have been obvious to one of ordinary skill in the art at the time

the invention was made to modify the modified Schuster's reference to include the steps of calculating time period between inhalations as taught by Krumbiegel in order to ascertain more information about a patient's breathing pattern.

9. Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schuster et al. (5,906,202), Mishelevich et al. (5,363,842), Crockford et al. (2003/0205229), and Krumbiegel et al. (5,928,156) as applied to claim 13 above, and further in view of Strom (6,240,920).

In regards to claim 14, the modified Schuster's reference teaches all the limitations as discussed above but is silent as to including the method step of calculating the I:E ratio and comparing it to a third threshold value for adjustment to the pre-set time period. However, Strom teaches a method of operation for a ventilation system which discloses the importance of I:E ratio (Strom col. 2 ln. 12-14) and making adjustments to the gas delivery time based on this ratio (Strom col. 4 ln. 40-42). Strom does not explicitly mention comparison to a third threshold value for adjustment of pre-set time period, however comparison to a threshold value or target envelope is taught by Mishelevich and would have been obvious to one of ordinary skill in the art to apply a threshold value to the I:E ratio. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Schuster's reference to include the steps of calculating I:E ratio and adjusting the pre-set time based on comparison to a third threshold value as taught by Strom in order to ensure that the patient has the proper time to execute full inspiration and expiration patterns.

In regards to claims 15-17, the modified Schuster's reference does not explicitly mention values of a threshold for the I:E ratio however, this is considered to be a matter of design choice to one of ordinary skill in the art at the time the invention was made as the modified Schuster's reference would perform equally well with the claimed threshold values. Furthermore one of ordinary skill in the art at the time the invention was made would have found it obvious to decrease or increase the pre-set period of inhalation depending on whether the ratio was below or above the threshold value.

10. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Edgar et al. (4,677,975) as applied to claim 21 above, and further in view of Reinhold et al. (7,073,499).

In regards to claim 22, Edgar teaches all the limitations as discussed above however is silent as to providing an airflow regulator for restricting the speed of the inhaled airstream. However, Reinhold teaches an airflow regulator for an inhaler which includes a flow throttling structure which includes a baffle which acts as an airflow regulator (Reinhold col. 3 ln. 65-67 & col. 4 ln. 1-10). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Edgar to include an airflow regulator as taught by Reinhold in order to allow for a controlled varied flow rate delivered to the patient.

11. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Edgar et al. (4,677,975) as applied to claim 21 above, and further in view of Schuster et al. (5,906,202).

In regards to claim 26, Edgar teaches all the limitations as discussed above however is silent as to the controller being a microprocessor. However, Schuster teaches a aerosolizing delivery apparatus which is controlled by a microprocessor (Schuster 26). It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the controller 21 of Edgar with the microprocessor 26 as taught by Schuster in order to provide the controller with the ability to deduce the

timing and volume of aerosol and particle free air to be released into the patient's inspiratory cycle" (Schuster col. 13 ln. 34-36).

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following documents are considered to be pertinent art: Lanpher et al. (5,333,106) relates to an aerosol inhaler trainer, Hillsman (4,984,158) relates to a MDI biofeedback training system, and Dessertine (5,020,527) relates to an inhaler with timer means.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to COLIN STUART whose telephone number is (571)270-7490. The examiner can normally be reached on M-F 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/COLIN STUART/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771